

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 10-770V

Filed: May 16, 2016

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MADELYNE MEYLOR,

* TO BE PUBLISHED

*

Petitioner,

* Special Master Hamilton-Fieldman

*

v.

*

SECRETARY OF HEALTH
AND HUMAN SERVICES,

* Gardasil; Human Papillomavirus (HPV)

* Vaccine; Statute of Limitations; First

* Symptom or Manifestation of Onset;

* Premature Ovarian Failure (POF);

* Primary Ovarian Insufficiency (POI);

Respondent.

* Dismissal.

* * * * *

Mark Krueger, Krueger & Hernandez, SC, Baraboo, WI, for Petitioner.

Lara Englund, United States Department of Justice, Washington, DC, for Respondent.

DECISION¹

This is an action by Madelyne Meylor (“Petitioner”)² seeking an award under the National Vaccine Injury Compensation Program (hereinafter “Program”).³ Respondent contends that the petition was untimely filed, and as such should be dismissed. For the reasons set forth

¹ Because this decision contains a reasoned explanation for the undersigned’s action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the purposes espoused in the E-Government Act of 2002. *See* 44 U.S.C. § 3501 (2012). Each party has 14 days to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b).

² Petitioner was a minor at the outset of litigation; thus, until she reached her eighteenth birthday, the petitioners were her parents. Once she turned eighteen, the case caption was changed. But for ease of reference, the undersigned disregards this distinction in the present decision.

³ The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (hereinafter “Vaccine Act”), provides the statutory provisions governing the Program.

below, the undersigned concludes that the petition was untimely filed, and it is therefore hereby dismissed.

I. FACTUAL BACKGROUND

Petitioner was born on April 6, 1993. Pet'r's Ex. 1, ECF No. 8-2.⁴

On June 7, 2006, at thirteen years of age, Petitioner underwent a routine health screening and obtained normal results. Pet'r's Ex. 4 at 55-57, ECF Nos. 8-5 to 8-9. The associated record notes signs of sexual maturation, including breast development, and indicates that menarche⁵ occurred at 13 years of age.⁶ *Id.* at 56. Petitioner's menses, however, were irregular.⁷ *Id.*

Petitioner testified that she began to experience sleep disturbances, including insomnia and night sweats, in the spring of 2007, which coincided with the end of her eighth grade year.⁸ *Meylor Tr.* at 26.

⁴ Unless expressly provided otherwise, all citations refer to the exhibits in *Meylor*, not *Culligan v. Sec'y of HHS*, No. 14-318V.

⁵ Menarche is "the establishment or beginning of menstruation." Menarche, *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) (hereinafter "*Dorland's*"). Menstruation is "the cyclic, physiologic discharge through the vagina of blood and mucosal tissues from the nonpregnant uterus; it is under hormonal control and normally recurs, usually at approximately four-week intervals, in the absence of pregnancy during the reproductive period (puberty through menopause) of the female of the human." Menstruation, *Dorland's*.

⁶ Petitioner testified that her first period occurred in January or February 2007. *Meylor Tr.* at 11, ECF No. 60, 62, 66; *see also* Pet'r's Ex. 17 at 1, ECF No. 24-4. It is unclear why this record, made nearly six months earlier, reports menarche having already occurred.

⁷ In her affidavit, Petitioner stated that after her first period, she had irregularity for "about the next year." Pet'r's Ex. 17 at 1. She explained: "This meant that I could have my period one month, miss the next month or have my period on back-to-back months. At no time during this one year period did I ever go three months or more without my period." *Id.*; *see also Meylor Tr.* at 12.

⁸ Petitioner misspoke about these dates, incorrectly stating that "the end of eighth grade into freshman year of high school" was "2007 into 2008." *Meylor Tr.* at 26. The correct time frame was the spring of 2007 (end of eighth grade) and fall of 2007 (beginning of ninth grade). *Id.* at 21. Further, Petitioner's mother, Mrs. Meylor, testified that at the end of Petitioner's eighth

That summer, on July 26, 2007, Petitioner returned for another routine health screening. Pet'r's Ex. 4 at 9-11. She was 14 years of age. The record of that visit reflects a progression in sexual maturation; however, a gynecological examination was deferred. *Id.* at 59-60. Menses were again reported as irregular.⁹ *Id.* at 60. At this visit, Petitioner received her first dose of the HPV vaccine. *Id.* at 259. Following this vaccination, Petitioner reportedly experienced a site reaction, as well as headaches, cramping and joint pain. *Meylor Tr.* at 36 (testimony of Mrs. Meylor); *see also* Pet'r's Ex. 31 at 2, ECF No. 48-3 (Serena Colafrancesco et al., *Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/Inflammatory Syndrome Induced by Adjuvants*, *Am. J. Reproductive Immunology* (2013)).¹⁰ A second dose of HPV was administered on November 25, 2007. *Id.* at 8. After this November 25, 2007 vaccination, Petitioner "reported similar injection site related symptoms accompanied by sleep disturbances, such as insomnia and night sweats." Pet'r's Ex. 31 at 2.

Following these vaccinations, Petitioner continued to have irregular periods. Pet'r's Ex. 17 at 1-2; *Meylor Tr.* at 12-13. Petitioner testified that between the first and second vaccination, her periods were "[s]till irregular, but shorter in duration." *Meylor Tr.* at 12. After the second vaccination, they "became even more irregular to the point where [they] lasted one to two days, if that, very extremely light, and [they] just dwindled from there." *Id.* at 13.

Petitioner stated that "[b]eginning in January or February 2008, about one year after [she] had [her] first period, [her] irregular periods started becoming more irregular." Pet'r's Ex. 17 at

grade year, she "knew [Petitioner] had sleep issues." *Id.* at 37. Mrs. Meylor also noted that at this time Petitioner had headaches and anxiety and was depressed. *Id.*

⁹ This reported irregularity is consistent with Petitioner's affidavit and testimony that she had irregularity for "about the next year" after her first period in January or February 2007. *Meylor Tr.* at 11; Pet'r's Ex. 17 at 1. The "one year" would extend to January or February 2008. *Meylor Tr.* at 12.

¹⁰ Petitioner's medical history is presented as a case study in this article co-authored by her medical expert, Dr. Yehuda Shoenfeld. *See Meylor Tr.* at 148 (affirming that "Case 1" is Petitioner). The article discloses that Petitioner complained of these symptoms "10 days after the first injection." Pet'r's Ex. 31 at 2. Dr. Shoenfeld confirmed that this medical history was obtained from Petitioner's mother, and not from Petitioner's medical records. *Meylor Tr.* at 235. When asked by the undersigned whether he thought it was strange that this history was not reflected in the medical records, he replied in the negative, explaining that physicians vary in what they choose to write in a clinical chart, and that subjective complaints such as sleep disturbances are often not noted. *Id.* at 233-34. Petitioner's mother also testified that, as teenagers, her daughters were not very forthcoming with their doctors. *Id.* at 232-33, 37-38.

2. She explained that she would still menstruate “every month or every other month but they would only last a day or two and [the] bleeding was very light and . . . not the same in duration and amount of blood loss as the periods [she] had for about the first year.” *Id.*

On August 1, 2008, Petitioner received another health screening and was assessed as normal. *Id.* at 2-4. Inexplicably, the record notes that menstruation had not yet begun.¹¹ *Id.* at 4. A third dose of the HPV vaccine was administered at this visit. *Id.* She was 15 years of age. After the third vaccination, Petitioner “continued to experience the same symptoms: burning, pain and heavy sensation in the injected arm, headache and cramping. Insomnia associated with night sweats persisted and she started complaining of arthralgia, anxiety and depression. [She] reported that her last period occurred shortly after the last injection of the HPV vaccine.” Pet’r’s Ex. 31 at 2.

On August 14, 2009, Petitioner met with her gynecological health provider to discuss her lack of menstruation. *Meylor Tr.* at 86. During the consultation, she reported that her first period had occurred approximately three years prior,¹² after which she menstruated about every other month for one year. *Id.* at 87. She then ceased menstruating and had not had a period in almost two years. *Id.* The provider diagnosed her with secondary amenorrhea,¹³ ordered lab tests for FSH and estradiol levels, and prescribed a course of Provera. *Meylor Tr.* at 87. Petitioner was instructed to return if she did not have a period within two weeks of completing the medication. *Id.*

On September 16, 2009, Mrs. Meylor telephoned the gynecologist’s office to report that Petitioner had taken Provera for a week, but had not yet had a period. *Id.* at 86. On September

¹¹ Petitioner stated that the “very light periods that [she] previously described may have been occurring as of [this] time but definitely stopped within a few months following [her] third vaccination of August 1, 2008. *Id.* at 2; *see also Meylor Tr.* at 13-14.

¹² This would have placed menarche at approximately August of 2006, as initially noted in Petitioner’s pediatric records. *Supra* n.6. However, with regard to this notation in the medical record, Petitioner stated: “I do note that I did not have my first period in August of 2006 as implied by the reference to my first period being ‘about three years ago.’ However, I did turn 13 in the year 2006 and . . . had my first period toward the end of my 13th year which would have been in January or February of 2007.” Pet’r’s Ex. 17 at 2.

¹³ Amenorrhea is “absence or abnormal stoppage of the menses.” Amenorrhea, *Dorland’s*. Primary amenorrhea is “failure of menstruation to occur at puberty.” Primary Amenorrhea, *Dorland’s*. Secondary amenorrhea is “cessation of menstruation after it has once been established at puberty.” Secondary Amenorrhea, *Dorland’s*.

24, 2009, Mrs. Meylor was informed of Petitioner's lab test results, which showed elevated FSH and decreased estradiol. *Id.* at 82-84. She was advised to have Petitioner evaluated by an endocrinologist. *Id.*

On December 7, 2009, Petitioner was seen by Kathleen Gamoke, a physician's assistant in endocrinology, for an evaluation of secondary amenorrhea. *Id.* at 64-66. The history reflected in the record indicates Petitioner had her first period at the age of 13, with subsequent periods occurring every two months for one year; thereafter they stopped. *Id.* at 65. She denied any significant health problems, but did report a chronic sleep disturbance. *Id.* at 66. The plan was for additional lab testing and a pelvic ultrasound. *Id.* The ultrasound, performed on December 10, 2009, revealed a small uterus and normal ovaries and follicles. *Id.* at 247.

On January 11, 2010, Petitioner followed up with Ms. Gamoke to discuss the results of all of the testing that had been performed to date. *Id.* at 132-33. Genetic testing for Turner syndrome was negative, and although Fragile X syndrome results were pending, Ms. Gamoke anticipated they would be negative as well. *Id.* at 133. During the visit, Petitioner was informed that she appeared to have primary ovarian insufficiency ("POI")¹⁴ and would likely not be able to ever conceive spontaneously. *Id.* Ms. Gamoke recommended that Petitioner begin taking birth control pills for hormone replacement. *Id.*

II. PROCEDURAL BACKGROUND

On November 8, 2010, Petitioner filed the present action, alleging that the Human Papillomavirus vaccinations ("Gardasil" or "HPV" vaccines) administered to her on July 26 and November 15, 2007, and August 1, 2008, caused her to suffer from POI. Pet., ECF No. 1.

On December 15, 2010, the special master to whom the case was assigned held the initial status conference with the parties' counsel. *See* Minute Entry (Dec. 17, 2010). Thereafter, on

¹⁴ Although the parties and the undersigned initially used the term, "premature ovarian failure" or "POF" to define Petitioner's injury—it became clear from the literature filed by the experts that POI "is the preferred term for the condition that was previously referred to as [POF]. . . . The condition is considered to be present when a woman who is less than 40 years old has had amenorrhea for 4 months or more, with two serum FSH levels (obtained at least 1 month apart) in the menopausal range." *See* Pet'r's Ex. 15, Tab 1 at 1, *Culligan*, ECF No. 53-2 (Lawrence Nelson, *Primary Ovarian Insufficiency*, 360 New Eng. J. Med. 606, 606 (2009)) (hereinafter "Nelson" with pincites to Petitioner's pagination). Therefore, the undersigned will refer to the condition as POI.

December 30, 2010, Petitioner filed the required medical records and a statement of completion. *See* Statement of Completion, ECF No. 9.¹⁵

On March 18, 2011, Respondent filed her Rule 4(c) Report, wherein she argued both that the claim was untimely filed and that Petitioner had failed to carry her burden of proof under *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Resp’t’s Report at 4-8, ECF No. 12. As to the first argument, Respondent argued that the medical evidence “suggests that the first manifestation of [Petitioner]’s condition was sometime in late summer or early fall of 2007,” which would have been more than three years prior to the initiation of her claim. *Id.* at 4. Respondent asserted that unless petitioner “can provide evidence that the first manifestation of Petitioner’s condition was after November 8, 2007, this claim is time-barred.” *Id.* As to the second argument, Respondent noted that Petitioner had not submitted an expert report or medical literature to support her assertion that the HPV vaccine caused Petitioner’s POI and “[n]one of her treating physicians attributed her problem to the vaccines.” *Id.* at 6. Respondent additionally noted that Petitioner’s sister suffered from the same condition, which “strongly suggests that there may be a genetic cause.” *Id.* In Respondent’s view, Petitioner’s claim was “based entirely on a ‘*post hoc ergo propter hoc*’ line of reasoning (*i.e.*, [her] symptoms started after the vaccinations, therefore they were caused by the vaccinations).” *Id.* at 7.

Following a status conference on April 28, 2011, Petitioner was ordered to file a medical expert report. *See* Scheduling Order (Apr. 29, 2011), ECF No. 13. On February, 13, 2012, Petitioner filed the expert report of Dr. Shoenfeld, along with his CV and relevant medical literature. *See* Pet’r’s Exs. 7-16, ECF Nos. 23-2 to 24-3. Petitioner also filed an affidavit on her own behalf. Pet’r’s Ex. 17, ECF No. 24-4. The report and CV of a second expert, Dr. Orit Pinhas-Hamiel (“Dr. Hamiel”), were filed on March 22, 2012. Pet’r’s Exs. 18-19, ECF Nos. 25-2, 25-3.

On March 28, 2012, the special master convened a status conference to discuss Petitioner’s expert reports. *See* Minute Entry (Mar. 28, 2012). Due to certain deficiencies in the reports, Petitioner was ordered to file a supplemental report from Dr. Shoenfeld, and was given the option of filing a supplemental report from Dr. Hamiel. *See* Scheduling Order (Mar. 30, 2012) at 1-3, ECF No. 27.

On August 15, 2012, Petitioner filed Dr. Shoenfeld’s supplemental report, along with supporting medical literature. *See* Pet’r’s Exs. 22-27, ECF No. 31-2 to 31-7.

¹⁵ Additional medical records were filed on December 21, 2011, and March 27 and August 13, 2012. *See* Pet’r’s Exs. 5, 6, 20, 21, ECF Nos. 19-2 to 19-3, 26-2, 30-2. These records were reviewed by the undersigned, but will not be discussed here as they are not pertinent to the issue being decided.

Respondent filed responsive expert reports and CVs from Drs. Barry Bercu and Arnold Levinson on October 22, 2012. Resp't's Exs. A-D, ECF Nos. 32-1 to 32-4.¹⁶ Respondent filed relevant supporting medical literature on October 31, 2012. Resp't Exs. A1-A48, C1-C3.¹⁷

On February 20, 2013, the special master convened a status conference to discuss the parties' respective expert reports and to set deadlines. *See* Scheduling Order (Feb. 21, 2013), ECF No. 38. Among other things, the parties were ordered to identify dates for a two-day Entitlement Hearing. *Id.* at 3.

On February 21, 2013, Petitioner submitted a second supplemental expert report from Dr. Shoenfeld addressing the opinions of Drs. Bercu and Levinson. Pet'r's Ex. 28, ECF No. 36-2. Respondent's experts declined to respond to Dr. Shoenfeld's second supplemental report. *See* Resp't's Status Report (Mar. 8, 2013) at 1, ECF No. 40.

In response to the parties' input, an Entitlement Hearing was scheduled for November 7-8, 2013, in Washington, D.C., before the undersigned. *See* Hearing Order (Apr. 8, 2013); *see also* Order Reassigning Case, ECF No. 39. A status conference was held on May 2, 2013, to discuss the pending hearing and to set additional deadlines. *See* Scheduling Order (May 23, 2013), ECF No. 43. Another status conference was held on September 17, 2013, to further discuss the hearing and to establish a schedule for pre-hearing submissions.¹⁸ *See* Scheduling Order (Sept. 20, 2013). Petitioner and Respondent filed pre-hearing briefs on September 25, 2013, and October 24, 2013, respectively. Pet'r's Prehearing Submissions, ECF No. 50; Resp't's Prehearing Submissions, ECF No. 53.

The Entitlement Hearing was held as scheduled, *see* Minute Entry (Nov. 8, 2013), with additional testimony heard on February 6, 2014, *see* Minute Entry (Feb. 6, 2014). Petitioner

¹⁶ Respondent filed an updated CV for Dr. Levinson on November 20, 2013. Resp't's Ex. I, ECF No. 57-1.

¹⁷ Where no ECF citation is provided, the exhibit(s) was/were filed via compact disc.

¹⁸ The hearing was planned as a "dual hearing," in which the claims of Petitioner and her sister, Olivia, would be heard together. Scheduling Order (Sept. 20, 2013) at 1, ECF No. 49. During this status conference, the undersigned emphasized that despite being heard together, the claims "involve[d] two separate and unique individuals" who must be treated distinctly "even if there is great similarity between [their] cases." *Id.* The undersigned still felt that it was appropriate to have one hearing for both girls, but underscored that "the hearing would have to be conducted carefully." *Id.* For example, "Petitioners' experts could use the same theory of how the vaccines caused the injuries claimed for both girls"; however, "the experts for both sides would need to treat the girls as separate and distinct individuals" when offering their opinions. *Id.*

filed her post-hearing brief on March 14, 2014, and Respondent filed hers on April 4, 2014. Pet'r's Post Hr'g Br., ECF No. 68; Resp't's Post Hr'g Br., ECF No. 74.

In November 2014, this case was identified for inclusion with other POI cases in an “omnibus proceeding” established to address the question of what constitutes the first symptom or manifestation of POI. *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*, ECF No. 23. The answer to this question is integral to the undersigned's determination of whether each petitioner had filed her claim within the statute of limitations. *See* 42 U.S.C. § 300aa-16(a)(2) (2012) (requiring that petitions be filed prior to “the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of injury”).

The lead case in the proceeding was *Culligan*.¹⁹ In *Culligan*, Respondent opposed entitlement to compensation because the first symptom of the petitioner's POI was oligomenorrhea,²⁰ which she had experienced more than three years prior to the filing of her claim, making it untimely under 42 U.S.C. § 300aa-16(a)(2). *See* Resp't's Rule 4(c) Report at 3-4, *Culligan*, ECF No. 20.

At a *Culligan* status conference held on September 23, 2014, the undersigned discussed with the parties the necessity of establishing the date that the statute of limitations began to run in *Culligan* and other cases alleging an injury of POI caused by Gardasil in order to assess the timeliness of the claims. *See* Scheduling Order (Sept. 25, 2014) at 1, *Culligan*, ECF No. 22. The undersigned directed the petitioner in *Culligan*'s counsel, Mark Krueger, who is also counsel in the instant case, to begin the process of identifying other POI claimants for inclusion in an omnibus proceeding focused on the question of timeliness.²¹ *Id.*

On October 1, 2014, Mr. Krueger filed a status report in which he identified eight POI cases²² to be included in the undersigned's assessment of timeliness. *See* Pet'r's Status Report

¹⁹ Once *Culligan* had been designated as the lead case, all of the filings for the onset proceedings were completed in the *Culligan* case, and not in the trailing cases. This section of the procedural history is therefore derived from the *Culligan* case. Citations to the *Culligan* record are so noted.

²⁰ Oligomenorrhea is defined as “menstrual flow happening less often than normal, defined as at intervals of 35 days to 6 months; called also *infrequent menstruation*.” Oligomenorrhea, *Dorland's*.

²¹ Mr. Krueger represents all but one of the petitioners in the omnibus proceeding.

²² Petitioner identified *Culligan*; *Alexander v. Sec'y of HHS*, 14-868V; *Tilley v. Sec'y of HHS*, 14-818V; *Fishkis v. Sec'y of HHS*, 14-527V; *Lee v. Sec'y of HHS*, 14-258V; *Lydia McSherry v.*

(Oct. 1, 2014), *Culligan*. Petitioner subsequently named *Culligan* as the “test case” for timeliness. See Pet’r’s Status Report (Nov. 5, 2014) at 1, *Culligan*, ECF No. 25.

Another status conference was held on November 20, 2014, during which the parties agreed that “in all pending [POI] cases . . . an expert hearing [would] be held to address the question of what constitutes ‘the first symptom or manifestation of [POI] onset recognized as such by the medical profession at large.’” Scheduling Order (Nov. 24, 2014) at 1, *Culligan*, ECF No. 26 (citing *Cloer v. Sec’y of HHS*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc)). The undersigned explained that a timeliness determination would be made on the basis of the evidence presented at the *Culligan* hearing; similar hearings would *not* be conducted in the other POI cases, all of which would trail *Culligan* for purposes of timeliness determinations. *Id.* The undersigned added four additional POI cases²³ to the list of cases set to trail *Culligan*. *Id.* The undersigned also ordered that all parties seeking to be joined in the omnibus proceeding consent to share their medical records, see Scheduling Order (Nov. 24, 2014) at 2, *Culligan*, and all parties later obliged.

The parties and the undersigned proceeded to identify questions for the experts (to be researched and answered before the hearing) regarding the nature and timing of the first symptom or manifestation of onset of POI in the aforementioned cases. See, e.g., Order (Feb. 18, 2015) at 1, *Culligan*, ECF No. 37; Scheduling Order (Jan. 30, 2015) at 1, *Culligan*, ECF No. 36; Pet’r’s Status Report (Dec. 29, 2014) at 1, *Culligan*, ECF No. 31; Scheduling Order (Nov. 24, 2014) at 2, *Culligan*; Resp’t’s Status Report (Oct. 28, 2014) at 1, *Culligan*, ECF No. 24. The parties and their experts ultimately agreed that, except in *Culligan*, in which the entire medical record would be considered by the experts, the experts would “offer opinions regarding the onset issues in the trailing cases by considering the facts of those cases as hypotheticals.” Joint Status Report (Jan. 20, 2015) at 1, *Culligan*, ECF No. 33. To facilitate this process, Petitioner filed summaries of the facts of all twelve POI cases. See Pet’r’s Ex. 9, *Culligan*, ECF No. 34-2.²⁴ Except in *Culligan*, the experts were to rely on the factual summaries, in lieu of the medical

Sec’y of HHS, 14-154V; *Meghan McSherry v. Sec’y of HHS*, 14-153V; and *Stone v. Sec’y of HHS*, 13-289V. Pet’r’s Status Report (Oct. 1, 2014) at 1, ECF No. 23.

²³ The four added cases were *Chenowith v. Sec’y of HHS*, 14-996V; *Bello v. Sec’y of HHS*, 13-349V; *Olivia Meylor v. Sec’y of HHS*, 10-771V; and the instant case. *Id.* The petitioners in these cases were all represented by Mr. Krueger.

²⁴ A factual summary for another trailing POF case—*Smith v. Sec’y of HHS*, 14-1107V—was also filed in *Culligan*. See Order Appendix (Feb. 23, 2015) at 2-3, *Culligan*, ECF No. 39-1; see also Order (Jan. 30, 2015) at 1-2, *Culligan*, ECF No. 36; Order (Jan. 26, 2015), *Culligan*, ECF No. 35. The petitioner in *Smith* was represented by different counsel.

records themselves, to articulate their opinions regarding timeliness. *See* Joint Status Report (Jan. 20, 2015) at 1, *Culligan*.

At a status conference held on January 28, 2015, the undersigned set deadlines for the parties' expert reports regarding timeliness. *See* Order (Jan. 30, 2015) at 2, *Culligan*. The experts were directed to address all of the identified timeliness questions separately, "on a question-by-question basis." *Id.* at 1.

On February 19 and March 3, 2015, three additional cases,²⁵ all filed by Mr. Krueger, were added to the list of POI trailing cases. *See* Scheduling Order (Mar. 3, 2015) at 1, *Culligan*, ECF No. 45; Scheduling Order (Feb. 19, 2015) at 1, *Culligan*, ECF No. 38. Mr. Krueger subsequently filed factual summaries of the three new cases. *See* Pet'r's Exs. 10, 11, 12, *Culligan*, ECF Nos. 40-2, 41-2, 44-2.

On March 12, March 13, and April 29, 2015, Petitioner filed expert reports and supporting medical literature, all of which were purportedly limited to the issue of timeliness. *See* Pet'r's Ex. 13, *Culligan*, ECF Nos. 47-2 to 51-6; Pet'r's Ex. 15, *Culligan*, ECF Nos. 53-1 to 54-3; Pet'r's Ex. 17, *Culligan*, ECF Nos. 76-78. The expert reports were authored by Dr. Felice Gersh and Dr. Hamiel. *See* Pet'r's Ex. 13, Tab 1, *Culligan*; Pet'r's Ex. 15, Tab 1, *Culligan*. The reports filed by Drs. Gersh and Hamiel reflected that they had reviewed the medical records underlying all of the POI cases. *See* Pet'r's Ex. 13, Tab 1 at 12-13, *Culligan*; Pet'r's Ex. 15, Tab 1 at 17, *Culligan*.

The undersigned convened a status conference on April 1, 2015, after having reviewed Petitioner's expert reports. *See* Scheduling Order (Apr. 2, 2015) at 1, *Culligan*, ECF No. 55. The undersigned noted that, "notwithstanding the fact that Petitioner's onset experts have now reviewed the medical records associated with every [POI] case, Respondent's onset expert(s) will review only the cases' factual summaries, the *Culligan* record, and Respondent's list of hypothetical questions." *Id.* Also, having expressed some concern about the extent to which Petitioner's expert reports reflected an understanding of the relevant question regarding timeliness, the undersigned reiterated the following:

[T]he relevant date, for purposes of assessing onset under *Cloer*, is *not* the first point in time at which a definitive diagnosis could have been made; rather, it is the time at which the first symptom or manifestation of the allegedly vaccine-caused injury occurred. The onset experts must make this assessment with the benefit of hindsight, rather than placing themselves in the shoes of the treating,

²⁵ The cases were *Brayboy v. Sec'y of HHS*, 15-183V; *Garner v. Sec'y of HHS*, 15-143V; and *Vakalis v. Sec'y of HHS*, 15-134V.

diagnosing physicians. The parties are directed to address this issue as specifically as possible in their pre-hearing briefs.

Id. (full citation omitted).

Respondent then filed an expert report regarding timeliness, as well as relevant medical literature, on May 8, May 28, and June 1, 2015. Resp't's Ex. A to A.32, *Culligan*, ECF Nos. 57-1 to 59-6, 63-1 to 63-3, 66-1 to 67-4. Respondent's expert report was authored by Dr. David Frankfurter. Resp't's Ex. A at 6, *Culligan*.

At a status conference held on May 14, 2015, Respondent confirmed that, in preparing his expert report, Dr. Frankfurter had reviewed only the factual summaries submitted by Petitioner (and the medical record from *Culligan*). See Order (May 15, 2015) at 1, *Culligan*, ECF No. 61. Mr. Krueger agreed that, notwithstanding the fact that his experts had reviewed all of the medical records in all of the POI cases, "his experts would be referring to the factual summaries rather than to the medical records themselves" at the timeliness hearing. *Id.*

The parties filed their pre-hearing briefs simultaneously on June 1, 2015, see Pet'r's Prehearing Submissions, *Culligan*, ECF No. 65; Resp't's Prehearing Submissions, *Culligan*, ECF No. 69; and the hearing took place on June 16 and 17, 2015, see Minute Entry (June 18, 2015), *Culligan*. Petitioner's experts, Drs. Gersh and Hamiel, and Respondent's expert, Dr. Frankfurter, testified. Tr. at 4, 255, *Culligan*, ECF Nos. 81, 83.²⁶

On July 1, 2015, the undersigned issued an order identifying nine POI cases²⁷ "as presumptively precluded under the applicable statute of limitations." Order (July 1, 2015) at 1, *Culligan*, ECF No. 79. *Culligan* was included among the presumptively precluded cases. *Id.* The undersigned also identified six cases²⁸ that appeared to have been timely filed. *Id.* Having apprised the parties of these preliminary conclusions, the undersigned granted them additional time to file status reports identifying the cases in which they intended to contest this

²⁶ Unlike with the exhibits, all citations are to the transcript in *Culligan* unless provided otherwise.

²⁷ The instant case, as well as *Culligan*, *Chenowith*, *Fishkis*, *Garner*, *Lee*, *Lydia McSherry*, *Meghan McSherry*, and *Laughlin*. Order (July 1, 2015) at 1.

²⁸ *Alexander*, *Bello*, *Brayboy*, *Olivia Meylor*, and *Vakalis*. *Id.* The undersigned also identified as timely *Smith*, a trailing POF case that had been filed by a different attorney. *Id.* In *Tilley*, the undersigned directed the parties to file additional briefs regarding timeliness. *Id.*

determination and explaining what they had identified as the first symptom or manifestation of onset in each of those cases. *Id.* at 2.

On August 28, 2015, Respondent filed a status report in which she stated that she did not intend to contest the undersigned's preliminary findings in any of the presumptively timely cases filed by Mr. Krueger. Resp't's Status Report (Aug. 28, 2015) at 1, *Culligan*, ECF No. 84. In status reports filed on September 2 and 30, 2015, Petitioner argued that all of the preliminarily precluded cases were, in fact, timely. *See* Pet'r's Status Report (Sept. 2, 2015) at 2-7, *Culligan*, ECF No. 85 (addressing *Culligan*, *Chenowith*, *Garner*, *Lee*, *Lydia McSherry*, and *Madelyne Meylor*); Pet'r's Status Report (Sept. 30, 2015) at 1-2, *Culligan*, ECF No. 87 (addressing *Fishkis*, *Meghan McSherry*, *Stone*).

At a status conference held on October 13, 2015, the undersigned "informed the parties that, for purposes of an onset determination, the [POI] cases [would] be divided [into] two groups: petitioners who never menstruated . . . and the rest of the [POI] petitioners." *See* Scheduling Order (Oct. 14, 2015) at 1, *Culligan*, ECF No. 88.

Relevant post-hearing briefing²⁹ concluded on January 20, 2016. *See* Pet'r's Post Hr'g Br., *Culligan*, ECF No. 91; Resp't's Post Hr'g Brs., *Culligan*, ECF No. 94; Pet'r's Post Hr'g Reply Br., *Culligan*, ECF No. 95. Petitioner's claim is now ready for a determination of the first symptom or manifestation of onset of the alleged vaccine-related injury; and, relatedly, whether the Vaccine Act's statute of limitations bars the claim.

III. ANALYSIS

A. Applicable Legal Standard

Section 300aa-16(a)(2) of the Vaccine Act provides that, regarding

a vaccine set forth in the Vaccine Injury Table which is administered after [October 1, 1998], if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury.

42 U.S.C. § 300aa-16(a)(2).

This statute of limitations is not triggered by the administration of the vaccine, but

²⁹ Briefing addressing Petitioner's request for interim attorneys' fees is not relevant to the timeliness issue and is therefore not included in this discussion.

“begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought.” *Cloer*, 654 F.3d at 1335. “[E]ither a ‘symptom’ or a ‘manifestation of onset’ can trigger the running of the statute [of limitations], whichever is first.” *Markovich v. Sec’y of HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007).

“[I]t is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations.” *Carson ex rel. Carson v. Sec’y of HHS*, 727 F.3d 1365, 1369 (Fed. Cir. 2013), *reh’g & reh’g en banc denied*, 2013 WL 4528833 at *1. “A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury.” *Markovich*, 477 F.3d at 1357. While the symptom of an injury must be recognized as such “by the medical profession at large,” *Cloer*, 654 F.3d at 1335, even subtle symptoms that a petitioner would recognize “‘only with the benefit of hindsight, after a doctor makes a definitive diagnosis of injury,’” trigger the running of the statute of limitations, whether or not the petitioner or even multiple medical providers understood their significance *at the time*. *Carson*, 727 F.3d at 1369-70 (quoting *Markovich*, 477 F.3d at 1358).³⁰

There is no explicit or implied discovery rule under the Vaccine Act. *Cloer*, 654 F.3d at 1337. The date of the occurrence of the first symptom or manifestation of onset of the alleged vaccine-related injury “does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition.” *Id.* at 1339. Nor does it depend on when a petitioner knew or should have known of a potential connection between an injury and a vaccine. *Id.* at 1338 (“Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury.”); *see Markovich*, 477 F.3d at 1358 (“Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine

³⁰ Petitioner argues that “POI is a latent injury” and that “the first symptom of onset, in terms of the applications [sic] of the statute of limitations, can be subtle and can precede manifestation of onset by months or even years.” Pet’r’s Post Hr’g. Br. at 9. This argument has been made before: the Court of Federal Claims, in *Setnes v. United States*, 57 Fed. Cl. 175 (2003), “was concerned with the very subtle symptoms attributed with autism that can be easily confused with typical child behavior, and it distinguished the terms ‘symptom’ and ‘manifestation.’” *Markovitch*, 477 F.3d at 1357-58. The *Setnes* court’s interpretation of the “first symptom or manifestation of onset” language of the statute was rejected by *Markovich*, a ruling that has since been reaffirmed by the Federal Circuit en banc in *Cloer*. 654 F.3d at 1334-1335.

Act.” (internal quotation marks omitted)).³¹

B. Symptoms of POI Onset, Including Criteria for Distinguishing “Symptom” from “Normal”

Primary ovarian insufficiency can begin abruptly, *see* Tr. at 69; *see also* Nelson at 2-3; but it may also develop over several years, *see* Tr. at 70, 198-99, 398; *Meylor* Tr. at 447; *see also* Nelson at 2-3; Pet’r’s Ex. 17, Tab 50 at 2 (Paolo Beck-Peccaz & Luca Persam, *Premature Ovarian Failure*, 1 Orphanet J. Rare Diseases, at 2 (Apr. 2006)) (hereinafter “Beck-Peccaz”). Thus, a woman could have symptoms of POI for several years before actually ceasing menstruation or being diagnosed with POI. *See* Tr. at 70, 198-99, 398; *see also* Tr. at 319; Nelson at 2-3; Beck-Peccaz at 2. The experts agreed that the symptoms of primary ovarian insufficiency include menstrual irregularities, including primary and secondary amenorrhea, cycle and frequency irregularity, and excessive or prolonged bleeding; delayed menarche; lack of breast development and poor growth velocity; night sweats; hot flashes; sleep disturbances; mood changes; joint pain; recurring ovarian cysts; arrested puberty; and marked hirsutism. Tr. at 38, 57, 68, 319, 366; *Meylor* Tr. at 59-60, 68-70, 77, 410. Most of these symptoms are not “normal” for a woman under the age of 40. Petitioner therefore does not dispute that they can constitute the “first symptom or manifestation of onset” of POI for purposes of the Act’s statute of limitations.

In fact, both Petitioner’s experts and the medical literature *emphasize* the degree to which symptoms other than menstrual irregularity signify POI. In her expert report, Dr. Hamiel called hot flashes and night sweats the “hallmarks of the menopausal transition.” Pet’r’s Ex. 15 at 5, *Culligan*. At the *Meylor* hearing, both Dr. Hamiel and Dr. Shoenfeld testified, on multiple occasions, that sleep disturbances constituted a symptom of POI, *Meylor* Tr. at 47, 53, 60, 68, 77, 126, 130, 233, as are joint pains and emotional problems such as anxiety and depression, *Meylor* Tr. at 68-70. Of particular note, Dr. Shoenfeld attested that sleep disturbances are a “major

³¹ To the extent Petitioner argues that this interpretation of the Vaccine Act’s statute of limitations violates the Fifth Amendment on Equal Protection and Due Process Grounds, *see* Pet’r’s Post Hr’g Br. at 11-13, the undersigned concurs with the reasoning articulated in numerous decisions to the contrary, all of which hold that the Act’s statute of limitations does not violate the Constitution merely because it bars certain petitioners from bringing a claim before they knew, or even could have known, that their injuries were vaccine-related. *See, e.g., Cloer v. Sec’y of HHS*, 85 Fed. Cl. 141, 150-51 (2008), *rev’d on other grounds*, 603 F.3d 1341, *aff’d en banc*, 654 F.3d 1322 (Fed. Cir. 2011); *Leuz v. Sec’y of HHS*, 63 Fed. Cl. 602, 607-12 (2005); *Wax v. Sec’y of HHS*, No. 03-2830V, 2012 WL 3867161, at *6-8 (Fed. Cl. Spec. Mstr. Aug. 7, 2012); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 655-57 (S.D. Tex. 2004); *Reilly ex rel. Reilly v. Wyeth*, 876 N.E.2d 740, 753-54 (Ill. App. Ct. 2007).

criteria” for diagnosing the autoimmune disorder, POI, and explicitly clarified that sleep disturbances are “symptoms, . . . not signs.” *Id.* at 233. Furthermore, Dr. Bercu, Respondent’s expert, testified that sleep disturbance and night sweats were “more typical of premature menopause” than they were of normal pubertal development. *Id.* at 381-82. And the medical literature supports the attestations of Drs. Hamiel and Shoenfeld. *See* Nelson at 4; Pet’r’s Ex. 15, Tab 6 at 2, ECF No. 53-7 (Vincent T. Martin, *Migraine and the menopausal transition*, 35 Neurological Scis. S65, S66 (2014)); Resp’t’s Ex. A.1 at 6, ECF No. 57-3 (Corrine K. Welt, *Primary ovarian insufficiency: a more accurate term for premature ovarian failure*, 68 Clinical Endocrinology 499, 504 (2008)). Given this (and Petitioner’s failure to argue otherwise), the undersigned now concludes that the aforementioned symptoms (beyond menstrual irregularities and delayed menarche), constitute symptoms of POI.

At this point, the undersigned notes that the parties engaged in a lengthy dispute in this case and the related cases regarding whether and when menstrual irregularity and delayed menarche constitute symptoms of POI. Although an extensive discussion of the parties’ positions and the undersigned’s conclusion was warranted in the related cases, it is ultimately not dispositive of this case. Therefore, the undersigned merely reiterates her conclusion that menstrual irregularity constitutes a symptom when it meets the criteria specified in the ACOG Opinion. *See* Resp’t’s Ex. A.2, *Culligan*, ECF No. 57-4 (Comm. on Adolescent Health Care, Am. Coll. of Obstetricians & Gynecologists, *Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign*, Comm. Op. No. 349 (Nov. 2006)) (hereinafter “ACOG Opinion” or “ACOG Op.”). The ACOG Opinion provides the following specific conditions under which menstrual irregularity is sufficiently abnormal so as to constitute a symptom of POI³²:

Menstrual Conditions That May Require Evaluation

Menstrual periods that:

³² Petitioner also argues that irregular menstruation should not be considered the first symptom of POI because it “can be explained by other causes.” Pet’r’s Post Hr’g Reply Br. at 2-3. This argument has been repeatedly rejected by the Federal Circuit, and is equally as unpersuasive here. A symptom need not be exclusive to the particular injury alleged in order to be “the first symptom” of that injury for purposes of the Act. *See Markovich*, 477 F.3d at 1357 (“A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the significance of a symptom with regard to a particular injury.”); *see also Carson*, 727 F.3d at 1370 (holding that even where “[t]here is no question that speech delay can be indicative of several conditions, and in some circumstances may even be normal . . . it was not arbitrary and capricious for the Chief Special Master to find that the severe speech delay . . . was the first objectively recognizable symptom of autism, the alleged vaccine injury”).

- Have not started within 3 years of thelarche^[33]
- Have not started by 13 years of age with no signs of pubertal development^[34]
- Have not started by 14 years of age with signs of hirsutism^[35]
- Have not started by 14 years of age with a history or examination suggestive of excessive exercise or eating disorder
- Have not started by 14 years of age with concerns about genital outflow tract obstruction or anomaly
- Have not started by 15 years of age^[36]
- Are regular, occurring monthly, and then become markedly irregular^[37]

³³ Thelarche is “the beginning of development of breasts in the female.” Thelarche, *Stedman’s Medical Dictionary* (28th Ed. 2013) (hereinafter “*Stedman’s*”).

³⁴ Pubertal development is measured by assessing an individual’s stages of puberty using the Tanner growth chart, which is “based on pubic hair growth, development of genitalia in boys, and breast development in girls.” Tanner stage, *Stedman’s*. For purposes of the ACOG criteria, the undersigned considers Tanner stages I (child) and II (prepubertal) as showing “no signs of pubertal development,” and Tanner stages III (early pubescent) and IV (late pubescent) as showing such signs. Dr. Frankfurter testified that a young woman who has never menstruated and who has no signs of secondary sexual development by age 13 should be evaluated. Tr. at 377.

³⁵ Hirsutism is the “presence of excessive bodily and facial hair, usually in a male pattern, especially in women.” Hirsutism, *Stedman’s*.

³⁶ At the hearing, Doctors Hamiel and Gersh opined that an adolescent who has not reached menarche by age 16 should be evaluated for primary amenorrhea. Tr. at 92, 238. Dr. Frankfurter opined that the age of evaluation should be 15 years. Tr. at 365. Both the ACOG Opinion and Dr. Hillard, author of medical literature introduced by Petitioner, acknowledge that the traditional definition of primary amenorrhea has been no menarche by age 16. ACOG Op. at 2; Pet’r’s Ex. 15, Tab 4, at 5, ECF No. 53-5 (Hillard, Paula, *Menstruation in Adolescents: What Do We Know? and What Do We Do with the Information?*, 27 J. Pediatric Adolescent Gynecology 309 (2014)) (hereinafter “Hillard” with pincites to Petitioner’s pagination). However, both articles note that 95-98% of females will have experienced menarche by age 15, and that delays in evaluating these young women can result in delays in detection and treatment of significant disorders, including POI. ACOG Op. at 2; Hillard at 6.

³⁷ At the hearing, Dr. Hamiel testified that she would recommend further evaluation of a non-adolescent woman whose cycle had been regular (21-35 days) and then became irregular (less frequent than every 35 days). Tr. at 67.

- Occur more frequently than every 21 days or less frequently than every 45 days^[38]
- Occur 90 days apart even for one cycle^[39]
- Last more than 7 days
- Require frequent pad or tampon changes (soaking more than one every 1-2 hours)

Id. at 5. But again, the undersigned repeats that the ACOG Opinion is only reproduced herein to provide context; unlike many of the related cases, it does not play a dispositive role in Petitioner's case.⁴⁰

C. Application of the Onset Symptom Criteria to the Present Case

Petitioner filed her petition on November 8, 2010, *see* Pet.; her petition is therefore time-barred if “the first symptom or manifestation of onset” of her alleged vaccine-injury, POI, occurred before November 8, 2007, *see* 42 U.S.C. § 300aa-16(a)(2). Petitioner asserts that the statute began to run sometime “between March and September 2008,” when she had her last period. Pet'r's Post Hr'g Br. at 4. Respondent asserts that the statute was triggered in “the spring of 2007” when Petitioner “began experiencing sleep disturbances, including insomnia and night sweats.” Resp't's Post Hr'g Br. at 2. Alternatively, Respondent points to Petitioner's pre-vaccination history of menstrual irregularity, which became more irregular “between her first vaccination in July 2007 and her second vaccination in November 2007,” as symptomatic of POI. *Id.*

Petitioner testified that she suffered from sleep disturbances, including insomnia and night sweats, beginning in the spring of 2007. Tr. at 26. Petitioner felt confident that this was the correct time frame because she recalled experiencing the symptoms at the end of the eighth grade. *Id.* (stating it was “[d]efinitely by the end of eighth grade”). At hearing, experts for both sides testified that sleep problems are a symptom of POI. *Meylor* Tr. at 47, 52, 68 (Dr. Hamiel); 291 (Dr. Levinson); 381-82 (Dr. Bercu).

³⁸ For women over the age of 18, this criterion is more frequently than every 21 days or less frequently than every 35 days. *See* ACOG Op. at 3; *see also* Tr. at 39 (documenting Dr. Hamiel's testimony normal menstrual frequency for a woman in her twenties is 21-35 days). The undersigned interprets this criterion to apply to frequency over two or more cycles.

³⁹ At the hearing, Dr. Hamiel testified that no menstruation for 90 days is not “normal.” Tr. at 79.

⁴⁰ Because Petitioner has no record of contraceptive use relevant to this case, the undersigned has entirely omitted any discussion of contraceptive use that, although dispositive in at least one of the related cases, would be wholly superfluous in this opinion.

During this same timeframe (spring into fall 2007), Petitioner was also experiencing joint pain, *Meylor* Tr. at 36; Pet'r's Ex. 7 at 4, ECF No. 23-2; and she was "very down, depressed," *id.* According to the experts, both joint pain and depression are symptoms of POI. *Meylor* Tr. at 69-70, 76 (joint pain); *Meylor* Tr. at 69, 410 (depression, mood changes).

The timing of these symptoms also makes sense in light of the experts' testimony. Dr. Hamiel, for example, testified that "[t]he decrease in estrogen [from POI] is gradual. It takes as long as a female in menopause. It may take years." *Meylor* Tr. at 71. Dr. Hamiel emphasized that "[y]ou don't lose all the ovary—all the cells immediately. It's not like a toxin that causes a bomb. It takes time until it happens . . . and it takes time until you lose all the follicles and until you discontinue to produce the estrogen." *Meylor* Tr. at 447. Moreover, she noted, "[t]he decrease in the estrogen level will result in symptoms that are typical to the menopause . . . fatigue, joint pain, sleeplessness, awakening in the middle of the night, mood changes, sweating." *Meylor* Tr. at 47.

Accordingly, the undersigned finds that the first symptom⁴¹ of Petitioner's POI—sleep disturbances—began in the spring of 2007.

IV. CONCLUSION

Based on the foregoing analysis, the undersigned finds that the first symptom of Petitioner's injury arose in the spring of 2007. Because that date precedes the statute of limitations deadline by at least a few months, the undersigned concludes that Petitioner's claim is time-barred. Her petition therefore must be, and is hereby, **DISMISSED**.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment herewith.⁴²

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master

⁴¹ The first symptom of Petitioner's POI may have arisen even earlier, given the documented history of menstrual irregularity dating to either spring of 2006, based on the medical records, or early 2007, based on Petitioner's affidavit and testimony. Ultimately, however, given the lack of specific information regarding the spacing of Petitioner's menstrual periods during the time (and the clear evidence documenting Petitioner's other symptoms), the undersigned makes no finding as to whether this irregularity was sufficient to constitute the first symptom of Petitioner's POI.

⁴² Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.